

whom the data and information are referred. The Food and Drug Administration will determine whether information submitted will be treated as confidential in accordance with the provisions of Part 20 of this chapter.

[45 FR 7484, Feb. 1, 1980]

§ 809.5 Exemption from batch certification requirements for in vitro antibiotic susceptibility devices subject to section 507 of the act.

(a) Antibiotic susceptibility devices subject to section 507 of the act are exempt from the batch certification requirements of Part 431 of this chapter if the following conditions are met:

(1) The antibiotic susceptibility device is approved for marketing under an appropriate antibiotic application.

(2) The antibiotic susceptibility device is packaged and labeled for dispensing in accordance with the applicable regulation (monograph) in this chapter except where other labeling has been approved in an applicable antibiotic application.

(3) The bulk antibiotic drug used in preparing the antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(4) The antibiotic susceptibility device meets the standards of identity, strength, quality, and purity specified in the applicable regulation (monograph) in this chapter except where other standards have been approved in an applicable antibiotic application.

(b) For each antibiotic susceptibility device subject to an exemption under this section, an approved antibiotic application is regarded to be an approved premarket approval application under section 515 of the act.

(c) Nothing in this section prevents a manufacturer from applying for batch certification of an antibiotic susceptibility device as provided in section 507(c) of the act.

(d) All exemptions from batch certification requirements for antibiotic susceptibility devices under this section

are subject to the conditions of effectiveness under § 809.6.

[47 FR 39160, Sept. 7, 1982, as amended at 53 FR 11252, Apr. 6, 1988]

§ 809.6 Conditions on the effectiveness of exemptions of antibiotic susceptibility devices from batch certification requirements.

(a) If at any time after an exemption from batch certification requirements for an antibiotic susceptibility device has been granted, the Commissioner finds on the basis of new information before the agency with respect to such exempted device evaluated together with the evidence available to the agency when such exemption was granted, that certification of each batch is necessary to ensure its safety and efficacy of use, the Commissioner shall act immediately to revoke all exemptions from batch certification requirements granted for such device.

(b) If the Commissioner finds that the person granted an exemption from batch certification requirements for an antibiotic susceptibility device has failed to comply with the requirements of section 507 of the act and the regulations promulgated thereunder; or if the Commissioner finds that the requirements of § 809.5 have not been met; or if the Commissioner finds that the petition for exemption from batch certification contains any false statements of fact, the Commissioner may revoke the exemption from batch certification requirements immediately and require batch certification of the device until such person shows adequate cause why the exemption from batch certification requirements should be reinstated.

(c) If the Commissioner repeals or suspends an exemption from batch certification requirements for an antibiotic susceptibility device, a notice to that effect and the reasons therefor will be published in the FEDERAL REGISTER.

(d) Any person who contests the revocation or suspension or denial of reinstatement of an exemption from batch certification requirements for an antibiotic susceptibility device shall have an opportunity for a regulatory hearing before the Food and Drug Administration under Part 16 of this chapter.

[47 FR 39160, Sept. 7, 1982]